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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,111	02/18/2004	Rogier Receveur	P10926.00	1950
27581	7590	04/03/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			BERTRAM, ERIC D	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,111

Applicant(s)

RECEVEUR ET AL.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The cancellation of claim 21 in the preliminary amendment filed 11/18/2004 is acknowledged.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Specification

3. The disclosure is objected to because of the following informalities: A reference to the prior application must be inserted as the first sentence(s) of the specification of this application, if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c).
4. Also, in line 4 of paragraph 0028, --be-- should be inserted immediately following "stylet may."

Appropriate correction is required.

Claim Objections

5. Claim 12 is objected to because of the following informalities: on line 2 of the claim, "an" should be deleted immediately following "cardiac." Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 8, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al. (US 6,474,341, hereinafter Hunter '341). Hunter '341 discloses an apparatus for determining the position of a catheter probe during a surgical procedure. Hunter '341 describes a catheter navigable within portions of an anatomical body, of which the heart would be included (Col. 3, lines 6-8). Disposed on the catheter is a sensor 22 which detects a magnetic field, the magnetic field being a physical parameter (Col. 3, lines 40-45). A processor 18 is shown in figure 1 to be communicatively coupled with the sensor such that it receives the sensed physical parameters and manipulates the parameters into navigational data by computing a position of the sensor (Col. 5, lines 1-14). As shown in figure 1, a navigational output device 20 in the form of a monitor is communicatively coupled with the processor 18, wherein the position data is output by the output device 20 (Col. 5, lines 25-35).

8. Claims 1, 2, 5, 6, 8-12, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunter et al. (US 2004/0097806, hereinafter Hunter '806). Hunter '806

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discloses a catheter 52 that is navigable within a cardiac anatomy (para 0043). Disposed on the catheter is a plurality of sensors 58, including pressure, optical, oxygen, temperature and electromagnetic sensors for sensing physical parameters (para. 0043 and 0067 and 0076). As shown in figure 1, the sensors are communicatively coupled with workstation 34, which inherently includes a processor. The workstation receives the physical parameters and manipulates them into navigational data (para. 0016 and 0049). The workstation is then communicatively coupled to a display 36, which displays navigational data relating to the sensors and the catheter (para. 0049). Hunter '806 further discloses an imaging device 12 which provides patient image data that is displayed in association with sensed parameters, including from magnetic field sensors as well as physical parameters from the body such as temperature and pressure (para. 0049). By combining this information, one can receive visual direction and confirmation to an anatomical location.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter '806. Hunter '806 discloses a method for navigating a lead in cardiac anatomy, including passing a lead with a temperature sensor into the vena cava. As described in paragraph 0076, the temperature of the current position is known, as is the temperature of the desired position, and is displayed graphically in a pop-up window. Thus, by comparing the temperature of the current position with the temperature of the desired position, one is able to confirm if the lead is placed in the desired position or if it is moving in the right direction. While Hunter '806 does not explicitly disclose the location of the right atrium, or that the landmark location is the coronary sinus, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use this method since it is used for other cardiac anatomy (vena cava) and as such would be applicable for use in the right atrium and coronary sinus.

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13. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter '806 in view of Lesh et al. (US 5,385,148, hereinafter Lesh). Hunter '806, as described above, discloses the applicant's basic invention with the exception of disclosing that the temperature sensors can be a thermistor or a thermocouple.

Attention is directed to the secondary reference of Lesh, who discloses an implantable lead utilizing a temperature sensor comprising a thermistor or a thermocouple (Col. 5, lines 40-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use a thermistor or a thermocouple as a temperature sensor on an implantable lead since their use is old and well known in the art.

14. Claims 7, 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter '806 in view of Zanelli et al. (US 6,024,703, hereinafter Zanelli). Hunter '806, as described above, discloses the applicant's basic invention including outputting information to a physician. However, Hunter '806 does not disclose that the output is audible in nature. Attention is directed to the secondary reference of Zanelli, which discloses that the use of visual and audio outputs increase the safety of an implantable system (Col. 10, lines 46-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Hunter '806 by adding audio outputs in order to increase the safety of the system since the physician would not have to look at a screen to receive instructions, but could hear them while focusing on the procedure.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Canady et al. (US 6,480,111) and Vilsmeier et al. (US 6,783,536) both disclose navigational systems for implantable catheters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Eric D. Bertram
Examiner
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EDB